UNITED STATES DEPARTMENT OF COMMERCE
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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/042,498	04/24/87	O'BRIEN	6626

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EXAMINER	
HUFFERY, F	
ART UNIT	**PAPER NUMBER**
182	8

DATE MAILED: 12/20/88

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 9/28/88 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ——— days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice re Patent Drawing, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449
4. ☐ Notice of informal Patent Application, Form PTO-152
5. ☐ Information on How to Effect Drawing Changes, PTO-1474
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1 and 3-10 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 2 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 and 3-10 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☐ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 183.

The cancellation of claim 2 is made of record.

Upon reconsideration the phrase "an isolated, substantially purified" is not seen as enabled in the specification with regard to "substantially purified". It is suggested that "substantially purified" be deleted.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless-

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 3 and 4 are rejected under 35 U.S.C. 102 (b) as being anticipated by Masuno et al and Bast et al, for reasons of record.

Namely, Masuno et al disclose a monoclonal antibody, OC125, specific to distinct determinants on the surface of human ovarian cancer cells. Bast et al disclose monoclonal antibody, OC 125, which is specific to human ovarian cancer.

The instant antibodies appear to be the same as the antibodies of Masuno et al and Bast et al, since they both have the same specific reactivities. Even if the antibodies are not identical, it would have been obvious to one of ordinary skill in the art to produce a variety of monoclonal antibodies to the ovarian OC 125 antigen disclosed in the references, since it appears that the instant subunit is exposed on the OC 125 antigen because the reactivity obtained in the instant invention appears to be the same as that of the references, regardless of the immunogen used.

Claims 5-10 are rejected under 35 U.S.C. 103 as being unpatentable over Masuno et al and Bast et al in view of Pestka or the WO Patent, for reasons of record.

Masuno et al and Bast et al disclose as set forth supra. Pestka and the WO Patent disclose a two-site or sandwich assay employing polyclonal and monoclonal antibodies. A two-site assay is used to detect two distinct epitopes or determinants at two different sites on an antigen.

In the absence of unexpected results, it would have been obvious to one of ordinary skill in the art use the monoclonal antibodies of Masuno et al and Bast et al to detect ovarian cancer with the two-site or sandwich assay taught by Pestka or the WO Patent to obtain the expected result. The assembly into kit form the reagents necessary to detect ovarian cancer is an obvious convience and conventional in the art.

Applicant's arguments filed September 28, 1988 have been fully considered but they are not deemed to be persuasive.

Applicant alleges that the CA 125 antigen disclosed by the references is present not only in ovarian cancer but also in; 1) benign diseases, such as endometriosis and pelvic inflammation, 2) normal developmental processes and 3) normal cells. Applicant next directs the Examiner to pages 5 and 6 of the specification where it is stated that "normal tissue tested has failed to show the presence of this fraction of CA 125 molecule."

This argument is not deemed convincing of patentability.

While it is noted that the applicant has indicated that normal tissue tested did not have the claimed subunit, the antibodies disclosed in Masuno et al and Bast et al do indicate the presence of CA 125 in several normal tissues except normal ovarian tissue. However, it is not clear that the antibodies of Masuno et al and Bast et al do not react with the instant subunit of CA 125, since the applicant has not provided any indication as to which tissues were tested.

Claim 1 is allowable over the prior art of record.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). The practice of automatically extending the shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 CFR 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Florina B. Hoffer at telephone number 703-557-8175.

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12/11/88

Robert J. Warden
ROBERT J. WARDEN
SUPERVISORY PATENT EXAMINER
ART UNIT 182